Sponsor/Applicant:	Reverse Medical Corporation 13700 Alton Parkway, Ste. 167 Irvine, CA 92618
Date Prepared:	May 17, 2014
Contact Person:	Jane Metcalf Vice President, Quality, Regulatory and Clinical Affairs Email: jmetcalf@reversemed.com
Trade Name:	Reverse Medical® MVP® Micro Vascular Plug System
Common Name:	Vascular Embolization Device
Classification Name:	Vascular Embolization Device
Device Classification :	Class 2
Regulation Number:	870.3300 (product code: KRD)
Predicate Devices:	Reverse Medical MVP-3 (K123803) and Reverse Medical MVP-5 (K133282)

Purpose of Submission

The purpose of this special 510(k) submission is to obtain market clearance for two (2) modifications to the MVP System. The first is to replace the electrolytic detachment method with a mechanical detachment method. The second is to reduce the length of the delivery wire from 180 cm to 160 cm.

Indication for Use and Intended Use

The Reverse Medical® Corporation MVP® Micro Vascular Plug System is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.

Device Description

Reverse Medical® MVP® Micro Vascular Plug System consists of a micro vascular occlusion plug that is attached to a composite delivery wire and is intended to be delivered to the treatment site through a catheter. The MVP occlusion plug is a self-expandable, ovoid-shaped frame made from nitinol and incorporates a PTFE cover over the proximal portion of the ovoid. The plug device is secured at both ends with platinum marker bands. The proximal marker band is attached to a delivery wire that is used to push the plug device through a commercially available catheter to the intended treatment site. After satisfactory deployment of the plug device at the treatment site, the implant is detached from the delivery wire by rotating the wire counter clockwise.

Technical Characteristics

The modified devices have the same technological characteristics as the predicate devices except for the detachment method and length of delivery wire. The mechanical

detachment method eliminates the need for a software controlled detachment box and cables. Table 5-1 compares characteristics of the modified devices to the predicates.

Table 5-1 Comparison to the Predicates

	K123803	K133282	Subject of this Submission	
Feature	**MVP-3 Predicate**	**MVP-5 Predicate**	**MVP-3 Modified**	**MVP-5 Modified**
Indications for Use	To obstruct or reduce the rate of blood flow in the peripheral vasculature.	To obstruct or reduce the rate of blood flow in the peripheral vasculature.	To obstruct or reduce the rate of blood flow in the peripheral vasculature.	To obstruct or reduce the rate of blood flow in the peripheral vasculature.
Materials of Construction	Nitinol, PTFE, Platinum, SS 301, Solder, Polypropylene sheath, Urethane, Cyanoacrylate	Nitinol, PTFE, Platinum, SS 301, Solder, Polypropylene sheath, Urethane, Cyanoacrylate	Nitinol, PTFE, Platinum, Solder, Polypropylene sheath, Urethane Cyanoacrylate	Nitinol, PTFE, Platinum, Solder, Polypropylene sheath, Urethane Cyanoacrylate
Plug (Implant) descripton	Self-expandabable, ovoid shaped frame with a PTFE cover over the proximal portion	Self-expandabable, ovoid shaped frame with a PTFE cover over the proximal portion	Self-expandabable, ovoid shaped frame with a PTFE cover over the proximal portion	Self-expandabable, ovoid shaped frame with a PTFE cover over the proximal portion
Plug Diameter, Unconstrained	5.3 mm	6.5 mm	5.3 mm	6.5 mm
Plug Length, Unconstrained	12 mm	12 mm	12 mm	12 mm
Target Vessel Diameter	1.5-3.0 mm	3.0-5.0 mm	1.5-3.0 mm	3.0-5.0 mm
Method of Placement	Delivery wire through a 0.021" ID Microcatheter	Delivery wire through a 0.027" ID Microcatheter	Delivery wire through a 0.021" to 0.027" ID Microcatheter	Delivery wire through a 0.027" ID Microcatheter
Radiopaque Markers	Platinum marker bands at each end of the plug	Platinum marker bands at each end of the plug	Platinum marker bands at each end of the plug	Platinum marker bands at each end of the plug
Proximal End of Plug Config.	Proximal marker band attached to delivery wire	Proximal marker band attached to delivery wire	Proximal marker band attached to delivery wire	Proximal marker band attached to delivery wire
Delivery Wire Length	180 cm	180 cm	160 cm	160 cm
Detachment System	Electrolytic	Electrolytic	Mechanical	Mechanical
Sterilization Process	EO	EO	EO	EO
Accessories	Electrolytic Box and Cables	Electrolytic Box and Cables	Torquer	Torquer

Performance Tests – Non-clinical

Due to the change in detachment method and delivery wire length the following design verification tests were conducted in accordance with Reverse Medical Design Control procedures. All testing was performed on units that were sterilized and met all inspection criteria. Tests on the Reverse Medical MVP System included:

- Dimensional Inspection
- Visual Inspection
- Microcatheter Compatibility within "Simulated Use Vascular Model"
  - Flexibility within microcatheter
  - Delivery wire kinking assessment
  - Multiple deployments and withdrawals through the microcatheter
  - Force required to deploy and retract device within the microcatheter
- Detachment Evaluations
  - Number of turns required to detach
  - Torque strength of detachment junction
- Galvanic Corrosion per ASTM G71
- MRI Compatibility per ASTM F-2503
- Package Integrity and Shelf-life

All tests successfully passed acceptance criteria. This demonstrates that the modified devices meet the product specification.

Basis for Determination of Substantial Equivalence

Upon reviewing the performance data and comparing intended use, design, materials, principle of operation and overall technological characteristics, the modified Reverse Medical MVP System is determined to be substantially equivalent to the currently marketed Reverse Medical MVP System. Differences between the systems do not raise any issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 18, 2014

Reverse Medical Corporation
% Jane Metcalf
VP, Quality Assurance, Regulatory and Clinical Affairs
13700 Alton Parkway, Suite 167
Irvine, California 92618

Re: K141313
Trade/Device Name: MVP Micro Vascular Plug System
Regulation Number: 21 CFR 870.3300
Regulation Name: Device Embolization, Vascular
Regulatory Class: II
Product Code: KRD
Dated: May 16, 2014
Received: May 20, 2014

Dear Ms. Metcalf,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141313

Device Name
Reverse Medical(R) Corporation MVP(R) Micro Vascular Plug System

Indications for Use *(Describe)*
The Reverse Medical(R) Corporation MVP(R) Micro Vascular Plug System is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Kenneth J. Cavanaugh -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

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